UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	)	Judge Patti B. Saris

UNITED STATES' RESPONSE TO ROXANE DEFENDANTS' SUPPLEMENTAL LOCAL RULE 56.1 STATEMENT OF MATERIAL FACTS

I. The DMERCs' Drug Classifications And Procedures Were Not Publicly Available, And Were Unknown To Roxane.

319. The Cigna and Palmetto Durable Medical Equipment Regional Carriers ("DMERCs") confirmed that the Cigna and Palmetto Medicare pricing arrays, which reflected the classification of Novaplus ipratropium bromide as a brand for most time periods, were not publicly available. (Tab 336, 10/14/09 Stone Dep. 156, Tab 337, 10/16/09 Helton Dep. 76-77; *see also* Tab 338, Roxane SOF ¶ 162)

United States' Response: The United States does not dispute that Cigna and Palmetto did not publicly disseminate their pricing arrays. The United States disputes, however, the suggestion that the pricing arrays were "secret" or not "available" to Roxane, as Roxane could have obtained the information upon inquiry through, for example, a Freedom of Information Act Request.

320. The Cigna and Palmetto DMERCs testified that a manufacturer, like Roxane,would not know that the DMERCs classified Novaplus ipratropium bromide as a brand as opposed to a generic drug. (Tab 337, 10/16/09 Helton Dep. 78-79, 116-18; Tab 336, 10/14/09 Stone Dep. 156)

United States' Response: The United States does not dispute that Cigna and Palmetto did not publicly disseminate their pricing arrays. The paragraph is otherwise disputed. Roxane was on notice that, pursuant to CMS instructions and criteria published in the Federal Register, the DMERCs (including Cigna and Palmetto) classified a brand as "any product that is marketed under a name other than the generic chemical name of the drug." 63 Fed. Reg. 58,814, at 58,849-50. Roxane knew that "NovaPlus" was a brand name, and Roxane marketed NovaPlus ipratropium bromide under that brand name. *See generally* United States' Responses to Paragraphs 141 - 143. Accordingly, Roxane was on notice that its NovaPlus ipratropium bromide products were likely to be classified as brands. Further answering, Roxane could have submitted a Freedom of Information Act request for the pricing arrays showing that NovaPlus ipratropium bromide was classified as a brand.

321. The Palmetto DMERC testified that the DMERCs' "internal procedures," such as the Desk Procedures outlining how to classify drugs by reviewing capitalization formats in the paper version of Redbook, were also not publicly available (Tab 336, 10/14/09 Stone Dep. 29, 39-40), and were created by Blue Cross/Blue Shield as the Medicare Part B carrier for South Carolina. (*Id.* at 29-31)

United States' Response: The United States does not dispute that the "Desk Procedure" was not publicly disseminated. Further answering, Roxane offers no evidence to support a finding that the Drug Pricing Procedure has any bearing on whether or not the NovaPlus ipratropium bromide product was properly classified as a brand product. By 1999, the DMERCs were using quarterly CD-ROM updates to the Red Book, which listed products by their full name. Fauci Exhibit 163 (Stone Decl.), ¶¶ 8-9; Henderson Common Exhibit 3 (Helton Decl.), ¶¶ 29-31; *see supra* United States' Response to Paragraph 180.

322. The DMERCs were allowed by regulation and HCFA directives to use various published compendia such as Redbook, FirstDatabank Bluebook, or Medispan.

(Tab 338, Roxane SOF ¶ 163; Tab 337, Helton Dep. 10/16/09 64-65; Tab 336, 10/14/09 Stone Dep. 65-66)

United States' Response: Undisputed.

323. In practice, however, the DMERCs limited their review to Redbook, and never looked to other compendia such as FirstDatabank Blue Book or Medispan to determine whether a drug was a brand or a generic. (Tab 337, 10/16/09 Helton Dep. 62-63, 65; *see also* Tab 336, 10/14/09 Stone Dep. 60; Tab 338, Roxane SOF ¶¶ 214-220)

United States' Response: The United States does not dispute that the DMERCs primarily looked to Redbook to determine AWPs. The United States disputes, however, that the DMERCs relied on Redbook to "to determine whether a drug was a brand or a generic." On the contrary, the DMERCs determined whether a product was a brand or a generic based on whether the product had a label name other than the generic chemical name of the drug. Fauci Supplemental Exhibit 191 (10/14/2009 Stone Dep.), at 160:12 - 162:2; Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 128:17 - 130:13. Ms. Helton, the corporate representative of Cigna, testified that information contained in the Redbook helped her determine whether a product was a brand or generic, but that the determination was ultimately based on CMS instructions:

> Q. Okay. And we'll talk about the CDs in just a moment. But just so I understand how it worked at Cigna, it -- you would apply the rule regarding capitalization of the product to determine whether it was a generic or brand when you were relying on the hard copy Red Book; is that correct?
> MR. FAUCI: Objection to the form.
> A. THE WITNESS: The capitalization of the product helps you determine. You would apply the rules that are in the CMS guidelines.

Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 46:18 - 51:1.

324. The DMERCs' decision to limit their review solely to Redbook was not public and was based on familiarity and a convenience factor. (Tab 336, 10/14/09 Stone

Dep. 62-66; *see also* Tab 337, 10/16/09 Helton Dep. 60-61, 115-16)

United States' Response: The United States does not dispute that the DMERCs did not publicize their decision to utilize the Redbook to determine AWPs. Further answering, *see supra* United States' Responses to Paragraphs 319 and 322.

II. The DMERCs' Classification Of Novaplus Ipratropium Bromide As A Brand Depended On The Format Of The Compendia Reviewed.

325. When compiling drugs into their Medicare pricing arrays, the DMERCs reviewed different versions of the Redbook pricing compendia, including CD-ROM databases and annual and monthly paper editions. (Tab 336, 10/14/09 Stone Dep. 37-38; *see also* Tab 338, Roxane SOF ¶ 166)

United States' Response: The United States does not dispute that, at different times, the DMERCs reviewed different versions of the Redbook pricing compendia to determine AWPs. Specifically, the DMERCs consulted the printed version of the Redbook prior to the end of 1999, and the quaterly CD-ROM versions of the Redbook thereafter. *See generally* United States' Response to Paragraph 180; Fauci Supplemental Exhibit 191 (10/14/2009 Stone Dep.), at 164:7 - 165:3; Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 59:14 - 61:7. After 1999, the DMERCs continued to use monthly paper editions of the Redbook, but only to check if changes had been made to the latest version of the quaterly CD-ROM. Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 127:8 - 128:17.

326. The Cigna DMERC testified that a manufacturer like Roxane would have no way of knowing which particular format of Redbook the DMERCs used to create their pricing arrays. (Tab 337, 10/16/09 Helton Dep. 115-16)

United States' Response: Undisputed that Roxane wouldn't "know" which version was used, but that information, although not publicized, was not secret. Roxane could have learned what version of Redbook the DMERCs were using to determine AWPs through, for example, a

Freedom of Information Act request.

327. Yet the classification of the Novaplus-label ipratropium bromide products as generics or brands in the DMERC pricing arrays depended on which format (hard copy versus electronic versions) of Redbook the DMERCs reviewed. (*Id.* at 95)

United States' Response: The United States disputes the materiality of this paragraph because the Cigna and Palmetto DMERCs used the CD-ROM version of the Redbook when they classified NovaPlus ipratropium bromide as a brand. Cigna and Palmetto classified NovaPlus ipratropium bromide as a brand because the product had a label name other than the generic chemical name of the drug. Fauci Supplemental Exhibit 191 (10/14/2009 Stone Dep.), at 160:12 - 162:2; Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 128:17 - 130:13. Hypotheticals are about what the DMERCs would have done had they used a different version of Redbook are speculative, inadmissable, and immaterial to this litigation.

Further answering, the United States does not dispute that *if* the DMERCs had used the hard copy of the Redbook, they would have classified NovaPlus ipratropium bromide as a generic product because, unlike the CD-ROM version, the hard copy did *not* list products by their full name. Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 57:9 - 59:8, 129:11 - 130:13. Ms. Helton, the corporate representative for Cigna, specifically testified that if the hard copy version of the Redbook listed NovaPlus ipratropium bromide by its full name, she would have classified NovaPlus ipratropium bromide as a brand product in accordance with CMS instructions. *Id.*

328. The DMERCs' methodology for classifying drugs as a generic or brand based on the paper Redbook was outlined in the Medicare Drug Pricing Procedure applicable to Medicare Part B and DMERC reimbursement. (Tab 338, Roxane SOF ¶¶ 180-81)

United States' Response: The United States disputes the materiality of this paragraph because

the Cigna and Palmetto DMERCs were using the CD-ROM version of the Redbook when they classified NovaPlus ipratropium bromide as a brand. Fauci Supplemental Exhibit 191 (10/14/2009 Stone Dep.), at 160:12 - 162:2; Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 128:17 - 130:13. Hypotheticals about what the DMERCs would have done had they used a different version of the Redbook are speculative, inadmissable, and immaterial to this litigation.

Further answering, the United States does not dispute that the Medicare Drug Pricing Procedure described how the DMERCs utilized the hard copy of Redbook to determine whether products were brands or generics. Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 46:18 - 51:1. The United States, however, disputes any implication that the Medicare Drug Pricing Procedure described the DMERCs' "methodology" for determining whether products were brands or generics. In accordance with CMS instructions, the DMERCs determined whether products were brands or generics by looking at whether the product had a label name other than the generic chemical name of the drug. Fauci Supplemental Exhibit 191 (10/14/2009 Stone Dep.), at 160:12 - 162:2; Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 128:17 - 130:13.

> 329. This methodology required the DMERCs to look at capitalization conventions and formats in the printed paper version of Redbook to determine whether a drug was a brand or generic (the "capitalization rule"). (Tab 336, 10/14/09 Stone Dep. 40-42; Tab 337, 10/16/09 Helton Dep. 44-48, 69-70; Tab 338, Roxane SOF ¶¶ 180-81) This capitalization rule was specific to the paper edition of Redbook. (Tab 336, 10/14/09 Stone Dep. 110-11; Tab 338, Roxane SOF ¶ 182)

United States' Response: The United States disputes the materiality of this paragraph, as the DMERCs were using the CD-ROM version of the Redbook when classifying NovaPlus ipratropium bromide. *See generally* United States' Responses to Paragraphs 327 - 328. Further

answering, the United States does not dispute that Medicare Drug Pricing Procedure instructed the DMERCs to refer to capitalization conventions when using the hard copy of Redbook to determine whether products were brands or generics.

330. The Palmetto DMERC testified that under the capitalization rule described in the Medicare Drug Pricing Procedure, the listing of Novaplus ipratropium bromide in the paper version of Redbook would cause her to classify Novaplus ipratropium bromide as a ***generic*** drug, and not a brand. (Tab 336, 10/14/09 Stone Dep. 47-48; *see also* Tab 338, Roxane SOF ¶¶ 185-210)

United States' Response: The United States disputes the materiality of this paragraph, as the DMERCs were using the CD-ROM version of the Redbook when classifying NovaPlus ipratropium bromide. *See generally* United States' Responses to Paragraphs 327 - 328. Further answering, the United States does not dispute that, if the DMERCs had used the hard copy of the Redbook, they would have classified NovaPlus ipratropium bromide as a generic because the product appeared in the printed Redbook as just "ipratropium bromide," and not as "ipratropium bromide - NovaPlus."

331. The Cigna DMERC also testified that under the capitalization rule described in the Medicare Drug Pricing Procedure, the listing of Novaplus ipratropium bromide in the paper version of Redbook would cause her to classify Novaplus ipratropium bromide as a ***generic*** drug, and not a brand. (Tab 337, 10/16/09 Helton Dep. 49-50, 58-59; *see also* Tab 338, Roxane SOF ¶¶ 185-210)

United States' Response: The United States disputes the materiality of this paragraph, as the DMERCs were using the CD-ROM version of Redbook when classifying NovaPlus ipratropium bromide. *See generally* United States' Responses to Paragraphs 327 - 328. Further answering, the United States does not dispute that, if the DMERCs used the printed version of the Redbook, NovaPlus ipratropium bromide would have been classified as a generic because the product appeared in the printed Redbook as just "ipratropium bromide," and not as "ipratropium bromide

- NovaPlus." Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 57:9 - 59:8, 129:11 - 130:13. Ms. Helton, the corporate representative for Cigna, specifically testified that if the hard copy of the Redbook listed NovaPlus ipratropium bromide by its full name, she would have classified NovaPlus ipratropium bromide as a brand product in accordance with CMS instructions. *Id.*

332. The Palmetto and Cigna DMERCs employed a different protocol when reviewing the CD-ROM version of Redbook. Specifically, the Palmetto and Cigna DMERCs looked to whether the product had some name in addition to or different from the generic chemical name of the drug (the "drug-name methodology"). (Tab 336, 10/14/09 Stone Dep. 49, 110-11, Tab 337, 10/16/09 Helton Dep. 57:9-14)

United States' Response: Disputed that Cigna and Palmetto employed a "different protocol" when reviewing the CD-ROM version of the Redbook. At all times, Cigna and Palmetto determined whether products were brands or generics based on whether the product had a label name other than the generic chemical name of the drug. Fauci Supplemental Exhibit 191 (10/14/2009 Stone Dep.), at 160:12 - 162:2; Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 128:17 - 130:13.

333. The Palmetto DMERC testified that this methodology of evaluating whether a drug's name contained the generic chemical compound name was a criteria that the DMERCs developed internally. (Tab 336, 10/14/09 Stone Dep. 67)

United States' Response: The United States states does not dispute that Ms. Stone, the corporate representative of the Palmetto DMERC, testified that the methodology of evaluating whether a drug's name contained the generic chemical compound name was developed "internally." Elsewhere, however, Ms. Stone testified that Palmeto relied on CMS guidelines in setting drug payments, including CMS' instruction that products having label names other than the generic chemical name of the drug were brands. Fauci Supplemental Exhibit 191

(10/14/2009 Stone Dep.), at 160:12 - 162:2.

334. The hard copy/paper editions of Redbook did not contain the word "Novaplus" anywhere in the listing for ipratropium bromide. (Tab 337, 10/16/09 Helton Dep.95; Tab 336, 10/14/09 Stone Dep. 134-35; *see also* Tab 338, Roxane SOF ¶¶ 189, 202)

United States' Response: Undisputed.

335. The Palmetto and Cigna DMERCs both testified that using the drug-name methodology looking at the paper Redbook would have still led them to classify Novaplus ipratropium bromide as a ***generic*** drug, and not a brand drug. (Tab 336, 10/14/09 Stone Dep. 135-36; Tab 337, 10/16/09 Helton Dep. 49-50, 57-59)

United States' Response: The United States disputes the materiality of this paragraph, as the DMERCs were using the CD-ROM version of the Redbook when classifying NovaPlus ipratropium bromide. *See generally* United States' Responses to Paragraphs 327 - 328. Further answering, the United States does not dispute that, if the DMERCs used the printed version of the Redbook, NovaPlus ipratropium bromide would have been classified as a generic because the product appeared in the printed Redbook as just "ipratropium bromide," and not as "ipratropium bromide - NovaPlus." Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 57:9 - 59:8, 129:11 - 130:13.

336. However, the drug-name methodology led to a different classification result for the Novaplus-label ipratropium bromide products when the DMERCs reviewed the Redbook electronic CD-ROMS, rather than the hard copy/paper versions of the Redbook. Both the Cigna and Palmetto DMERCs testified that they classified the Novaplus ipratropium bromide as a brand based on how it was listed on the Redbook CD-ROMs. (Tab 337, 10/16/09 Helton Dep. 95-96)

United States' Response: The United States disputes the materiality of this paragraph, as the DMERCs were using the CD-ROM version of the Redbook when classifying NovaPlus ipratropium bromide. *See generally* United States' Responses to Paragraphs 327 - 328. Further answering, the United States does not dispute that NovaPlus ipratropium bromide may have been

classified differently depending on which version of Redbook was used, because the hard copy version of Redbook did not list the product by its full name.

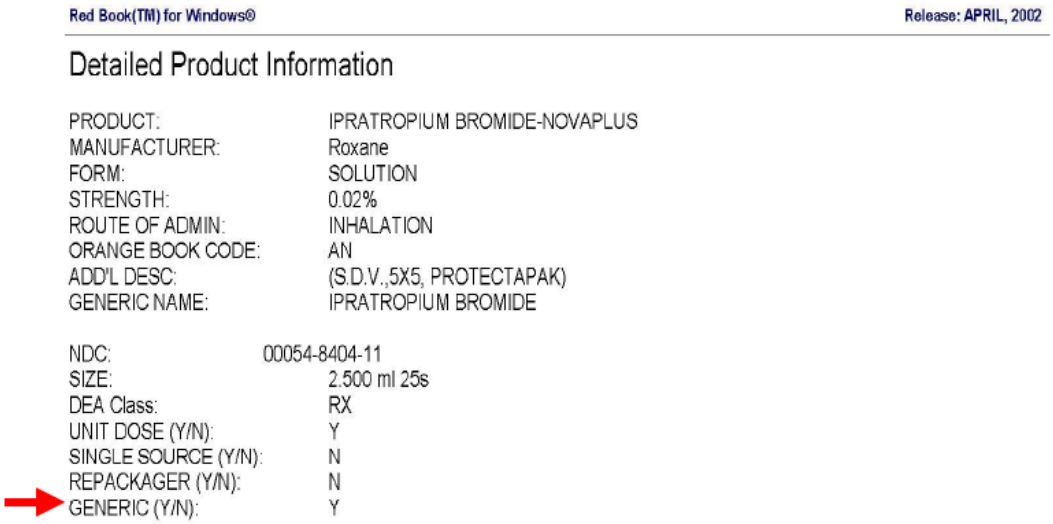
337. The DMERCs applied their drug-name methodology to the listings on the Redbook CD-ROMs and classified Novaplus ipratropium bromide as a brand even though the Redbook CD-ROMs used by the DMERCs contained a "generic field indicator" telling the DMERCs that the Redbook compendia classified Novaplus ipratropium bromide as a generic product. (Tab 336, 10/14/09 Stone Dep. 74-77; Tab 337, 10/16/09 Helton Dep. 84-85; Tab 339, Detailed Product Information Screens for Novaplus Ipratropium Bromide (CIGNA-0120-30, CIGNA-0131-41, CIGNA-0142-53, CIGNA-0154-65, CIGNA-0166-77, CIGNA-0178-89, CIGNA-0190-200, CIGNA-0201-11, CIGNA-0212-24, CIGNA-0225-40, CIGNA-0241-55); *see also* Tab, C Roxane SOF ¶ 182)

United States' Response: Undisputed. Answering further, Cigna and Palmetto did not rely on Redbook's categorization to determine whether products were brands or generics. Instead, in accordance with CMS instructions, Cigna and Palmetto looked to whether the product had a label name other than the generic chemical name of the drug. Ms. Helton, the corporate representative of Cigna, specifically testified that, in deciding whether or not the product was a brand or generic for purposes of Medicare reimbursement, she did not consider how Redbook classified the product.

Q. And for all three of these NDCs, the Red Book CD-ROM is telling you that these are also generic products, correct?
A. Yes.
Q. And it's telling you that because in the specific generic field it has a Y for yes for all three NDCs; isn't that right?
A. Yes.
Q. Now, did you take that information into account when you were classifying a Novaplus product in the Cigna arrays?
A. No.
Q. Can you explain why you didn't take that information into account?
A. I was looking specifically at the name of the drug, the name of the drug being different than the generic name, so I considered it a brand name.
Q. Okay. So the presence of the term Novaplus preceded by a dash would lead you to believe that it was a brand name versus a generic name?
A. Yes.

Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 84:20 - 85:20.

338. Specifically, the Redbook CD-ROMs that the Cigna and Palmetto DMERCs used contained the following screen applicable to the Novaplus-label ipratropium bromide NDCs, (Tab 339, Detailed Product Information Screens for Novaplus Ipratropium Bromide, at CIGNA 0187):



Red Book(TM) for Windows® Release: APRIL, 2002

Detailed Product Information

PRODUCT:	IPRATROPIUM BROMIDE-NOVAPLUS
MANUFACTURER:	Roxane
FORM:	SOLUTION
STRENGTH:	0.02%
ROUTE OF ADMIN:	INHALATION
ORANGE BOOK CODE:	AN
ADD'L DESC:	(S.D.V.,5X5, PROTECTAPAK)
GENERIC NAME:	IPRATROPIUM BROMIDE
NDC:	00054-8404-11
SIZE:	2.500 ml 25s
DEA Class:	RX
UNIT DOSE (Y/N):	Y
SINGLE SOURCE (Y/N):	N
REPACKAGER (Y/N):	N
GENERIC (Y/N):	Y

United States' Response: Undisputed.

339. The Palmetto DMERC testified that in the situation where the Redbook compendia CD-ROM that the DMERC relied upon classified a drug with a particular title as a generic drug, that created a potential ambiguity for the DMERCs. (Tab 336, 10/14/09 Stone Dep. 91-92)

United States' Response: Undisputed.

340. The Palmetto DMERC testified that certain words appended to a drug name would not trigger its classification as a brand, for example if the title contained a diluent, she might have consulted the medical staff to determine how to classify the drug. (*Id.* at 83-84)

United States' Response: Undisputed. Further answering, Ms. Stone testified that if a diluent appeared in the drug's name, that would "differ from a company placing what we call a branded name on the end" and would cause her to consult the medical staff. Fauci Supplemental Exhibit 191 (10/14/2009 Stone Dep.), at 83:5 - 84:4.

341. Unlike the Palmetto DMERC, the Cigna DMERC testified that she would have applied the drug-name method as an inflexible rule, stating any additional words in the title of a drug that were different from the words "ipratropium bromide"—including words such as Walgreens, CVS, or "this is a generic drug" would lead her to classify a drug as a brand. (Tab 337, 10/16/09 Helton Dep. 98-99)

United States' Response: Undisputed. Further answering, Ms. Helton testified that she had never seen products with the phrase "this is a generic drug" in the product name, and that such an unusual circumstance may have caused her to seek clarification from CMS. Fauci Supplemental Exhibit 192 (10/16/2009 Helton Dep.), at 98:20 - 99:6.

III. DMERC Testimony Confirms That Novaplus Ipratropium Bromide Never Set Medicare Payment Rates In The Real World.

342. Beginning in 1998, Medicare Part B payments were determined by comparing the median of all generic sources of a drug to the lowest available price for brand sources. (Tab 338, Roxane SOF ¶¶ 159, 174)

United States' Response: Undisputed.

343. The Palmetto DMERC testified that Palmetto's arrays contained a column containing a "G" or "B," which reflected whether the reimbursement rate for a particular J-code was set by the median of the generic sources, or by the lowest-priced brand source. (Tab 336, 10/14/09 Stone Dep. 22-25; *see also* Tab E, Stone Decl.¶ 12)

United States' Response: Undisputed.

344. A "G" in the column indicated that the rate for the drugs under a J-code was set by the median generic price, not the lowest brand price. (Tab 336, 10/14/09 Stone Dep. 26)

United States' Response: Undisputed.

345. For all of the quarters in which Novaplus ipratropium bromide was classified as a brand drug by the Palmetto DMERC, the column contained a "G," indicating that the allowable reimbursement rates for the pertinent ipratropium bromide J-codes was set by the median of the generic sources of ipratropium bromide. (Tab 336, 10/14/09 Stone Dep. 27-28)

United States' Response: Undisputed.

346. Thus, for every quarter that Novaplus ipratropium bromide was classified as a brand drug by Palmetto, Novaplus ipratropium bromide did not set the payment amount for ipratropium bromide in Palmetto's DME region. (*Id.* at 28; *see also* Tab 338, Roxane SOF ¶¶ 151-55 (outlining facts showing that Novaplus ipratropium bromide was rarely if ever reimbursed under Medicare Part B))

United States' Response: Undisputed.

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document and accompanying exhibits to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ *James J. Fauci*
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Dated: November 23, 2009